REMARKS/ARGUMENTS

Claims 1, 4-14 and 21-32 are pending following entry of the above amendments to the claims. The amendments to the claims and the addition of new claims 21 -32 find support in the originally filed claims and in the specification at, for example, page 3, lines 1-13 and in Examples 1 and 2.

Applicants acknowledge the Examiner's statement that in the pending claims, insulin, insulin analogs and insulin derivatives as the blood glucose regulator, and critically ill polyneuropathy (CIPNP) as the disease, are examined.

In response to the Examiner's objection to the specification as containing an embedded hyperlink on page 10, line 18, Applicants have amended the paragraph at page 10, lines 15-18 of the specification to delete the last sentence referring to the hyperlink.

OBJECTIONS TO THE CLAIMS

The Examiner objected to claims 4-5, 15 and 21 as containing recitations of non-elected diseases and blood glucose regulators and to claim 20 as reciting "mmole/L". In response, Applicants submit that these objections are rendered moot by the cancellation of claims 15 and 20-21 and by the amendments to claims 4-5 presented herein.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH

The Examiner rejected claims 1, 4-15 and 19-21 under section 112, first paragraph because the specification "while being enabling for a method of treating a critically ill polyneuropathy patient using insulin as a blood glucose regulator" (page 3 of present Office Action), does not reasonably provide enablement for claims to methods of treatment wherein the disease state of the patient and the structure of the blood glucose regulators are not defined.

In particular, the Examiner alleges that the specification "only discloses cursory conclusions without data supporting the findings, which state that the critical illness

in a patient or in a CIPNP patient can be treated or prevented by controlling glucose metabolism during the critical illness by applying intensive treatment with a blood glucose regulator such as insulin, active insulin derivatives or other blood glucose regulators" (page 4 of Office Action).

With all due respect, Applicants disagree.

Here, the present application provides far more than "cursory conclusions without data supporting the findings" as alleged by the Examiner.

In particular, the specification teaches that critical illness and/or CIPNP in a patient can be treated by strictly controlling glucose metabolism by utilizing blood glucose regulators to maintain the patient's blood glucose levels within specifically defined ranges; namely from about 60 to about 130 mg/dL; more preferably from about 70 to about 120 mg/dL and most preferably from about 80 to about 110 mg/dL (page 3, lines 1-13 of the specification).

This teaching and the specific blood glucose ranges recited in the specification as enabling the successful treatment of critically ill and CIPNP patients are not pulled from thin air. Rather, they are based on in vivo data from human patients demonstrating that strict control of blood glucose levels via administration of an exemplary blood glucose regulator, insulin, resulted in the successful treatment of both CIPNP patients (Example 1, page 17, lines 13-31) and critically ill patients[1] suffering from a variety of diseases and ailments such as need for mechanical ventilatory support, red cell transfusion and renal cell transplant (Example 2 and Tables 3 and 5 and also, page 22, lines 27-35 and page 25, lines 14-29).

Faced with this experimental data and a very specific and straight forward teaching by the present application that critically ill and CIPNP patients can be successfully treated by using blood glucose regulators to maintain the patient's blood gluscose levels within strictly defined levels, the Examiner alleges, without any supporting evidence, that the claimed invention is "highly unpredictable regarding the outcome of the treatment" (page 5 of Office

1 The Examiner stated that the working examples only demonstrated the "treatment of CIPNP with insulin" (page 5 of Office Action) but this is clearly not correct in view of Example 2

Action) and that "it is necessary to have additional guidance and to carry out further experimentation to assess the effects of various blood glucose regulators in the treatment of CIPNP or other critical illness" (pages 6-7 of Office Action).

However, as stated by the court in In re Marzocchi, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 169 USPQ 367, 370 (CCPA 1971).

Here, as of the filing date of the present application, numerous blood glucose regulators were widely available and prescribed to patients, including compounds such as sulfonylureas, thiazolidinediones and metformin, and the Examiner has provided no evidence why one of ordinary skill in the art would not have been able to use such blood glucose regulators to maintain blood glucose levels within the ranges taught by the present application as being effective to treat critically ill and CIPNP patients.

It is therefore Applicants' position that the Examiner has failed to satisfy the initial burden on the Patent Office to prove a prima facie case of nonenablement and withdrawal of this rejection is therefore respectfully requested

REJECTION OF THE CLAIMS UNDER 35 U.S.C. 112, SECOND PARAGRAPH

The Examiner rejected claims 1, 4-15 and 19-21 as indefinite because 1) claims 1, 4-15 and 19-21 omit the steps of an effective amount of a blood glucose regulator used and the outcome of the treatment; 2) the use of the term "and/or" in claims 1 and 4; 3) the use of the term "EMG" in claim 4; and 4) claim 5 depends from itself.

In reply, Applicants respectfully submit that these rejections are rendered moot by the amendments to the claims presented herein and withdrawal of the section 112, second paragraph rejections is therefore respectfully requested.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. 102 (b)

The Examiner rejected claims 1, 5, 6, 12 and 13 as rejected under section 102 (b) as anticipated by Rassias.

Applicants respectfully traverse this rejection.

The two pending independent claims, claims 1 and 4 are directed respectively to a method of treating a critically ill patient or a critically ill polyneuropathy (CIPNP)-patient comprising administering to the patient a blood glucose regulator in an amount effective to maintain blood glucose levels in said patient within a range of from about 60 mg/dL to about 130 mg/dL (claim 1) or to a method of treating a patient suffering from CIPNP (claim 4).

By comparison, Rassias describes a study in which diabetics that needed coronary bypass surgery showed reduced neutrophil phagocytic activity postoperatively when subjected to intensive insulin therapy as opposed to a more standard insulin therapy during surgery. Thus, Rassias did not teach treatment of CIPNP patients with a blood glucose regulator (claim 4) nor treatment of critically ill patients with a blood glucose regulator in an amount effective to maintain blood glucose levels in said patient within a range of from about 60 mg/dL to about 130 mg/dL (claim 1) (see Figure 1 of Rassias where mg% is mg/dL)[2]

Accordingly, in view of the above amendments and remarks, withdrawal of this rejection under section 102 (b) is respectfully requested.

The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

2 Applicants note that the absence of these limitations (CIPNP and blood glucose levels within the range of 60-130 mg/dL)from Rassias is also apparently acknowledged by the Examiner in the exclusion of originally filed

Please charge any deficiencies or overpayment to Deposit Account No. 14-1447.

Respectfully submitted,

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claims 7 (blood glucose levels within the range of 60-130 mg/dL) and 19 (treatment of CIPNP) from the present rejection.